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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/667,859	09/20/2000	Marek Z. Kubin	1010-US	1889

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EXAMINER	
LI, BAO Q	
ART UNIT	**PAPER NUMBER**
1648	12

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/667,859	KUBIN ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 March 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *03/26/2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☒ Applicant's reply has overcome the following rejection(s): *see attachment*.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *(see attachment)*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *None*.

Claim(s) objected to: *None*.

Claim(s) rejected: *73-78 and 80-89*.

Claim(s) withdrawn from consideration: *None*.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Bao Qun Li

Advisory Action

The response to the final action filed on March 26, 2003 under 37 CFR 1.116 has been entered. Claim 79 has been canceled and Applicants' response has been considered. However, it is not found persuasive to overcome the rejection. Therefore, the Application is not deemed to place the application in condition for allowance and will not be entered because:

For purpose of appeal, the status of the claims is as follows:

Allowed claim(s): NONE.

Rejected claim (s): 73-78 and 80-89.

Claim(s) objected to: NONE.

Sequence requirements

This application contains sequence disclosures **on line 20 of page 25, lines 10-11 and lines 13-14 of page 32** that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Claim Rejections - 35 USC § 112

1. Claims 73-78 and 80-89 are still rejected under 35 U.S.C. 112, first paragraph on the same ground as stated in the previous office action, because the specification, while being enabling for an isolated nucleic acid molecule consisting of SEQ IN NO: 1 and its coding amino acid sequence SEQ ID NO: 2, wherein its functional fusion proteins are made by its amino acid residues 1-221 with tags (SEQ ID Nos: 6-8), does not reasonably provide enablement for having any or all polynucleotide or amino acids fragment thereof having 80% homology to SEQ ID NO: 1 or 2 to be a functional molecule like NAIL. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

2. Applicants argue that examiner provide no reasons or evidence indicating why testing of a polypeptide for sequence identity, or the ability to bind CD48, would require undue experimentation.

3. Applicants asserted that specification or the method in the art teaches how to make and use nucleic acid molecule encoding additional NAIL polypeptides because the cDNA (SEQ ID NO: 1) and amino acid sequence SEQ ID NO: 2 are provided, it is straight forward to determine what variations of these nucleotide and amino acid sequences falls within the 80% sequence identity limitation recited in the claims.

4. Applicants' argument has been fully considered; however, it is not found persuasive. While specification has described how to calculate the homology or identity of a possible variants of NAIL, it does explicitly teach how to make each of the claimed products, for example, which 20% or 19% of amino acid can be varied and how to vary them etc.

5. The undue experimentation also manifested with the fact that one amino acid mutation can turn out to be a functional different molecule, i.e. the amino acid sequence of human chemokines, such as MIP-2α, MIP-2β and human GRO/MGSA (Robin et al. The cytokine Factors Book, Academic Press 1994, pp. 189) as described in the previous Office Action.

6. Therefore, considering the broad scope of the claimed invention, it is still concluded that the skilled artisan would have had to conduct undue and excessive experimentation in order to practice the claimed invention. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention

8. Claims 73-89 are still rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed any or all polypeptide having at least 80% or 90% homology to the certain amino acid fragments of SEQ ID NO:2.

9. Applicants traverse and continue argue that the examiner has incorrectly applied the facts of Eli Lilly Co. because Applicants cloned the human cDNA that encodes NAIL and identify the NAIL binding partner are CD48. Moreover, Applicants described a wide variety of variants of these molecules mutations, conserved changes, deletions, fusions to sequences encoded usually domains such as Fc's etc.).

10. Applicants' argument has been respectfully considered; however it is not found persuasive because the specification has been carefully reviewed, Applicants has disclosed an isolated full cDNA of NAIL with SEQ ID NO 1 and its full length of amino acid sequence of SEQ ID NO: 2, wherein the NAIL polypeptide consists of a single peptide of amino acids 1-21 of SEQ ID NO: 2, and extracellular domain of amino acids 220-221 of SEQ ID NO: 2, a transmembrane domain of amino acids 222-245 of SEQ ID NO: 2, and cytoplasmic domain of amino acids 246-365 of SEQ ID NO: 2. While Applicants states in the specification that variants of NAIL can occur naturally or derived from the disclosed SEQ ID NO: 2, Applicants only present the functional NAIL polypeptide variants of SEQ ID Nos 6-8. However, applicant does not have the possession of any other molecules having at least 80% or 90% identical to the amino acids 1-221 or 22-221 or 19-221 or SEQ ID NO: 2 besides SEQ ID NO: 6-8, which exhibit functions of NAIL. Therefore, the claims 73-78 and 80-89 are still rejected under the 35 U.S.C. 112 1st paragraph.

Claim Rejections - 35 USC § 103

11. The Office Action made by the previous Office Action on 103 of claims 73 to 84 is not in error because the rejection was based on the new claims 73-84, which can not completely read on the same scope of the previous rejected and canceled claims 48-50, 54-57 and 59.

12. Claims 73-78 and 80-89 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Valiante et al. (US Patent No. 5,688,690A), Sambrook et al. (Molecular Cloning A

laboratory Manual, 2nd edition, Cold Spring Harbor, N.Y. 1989, pp. 2.43-2.84) and Porunellor et al. (J. Immunol. 1993, Vol. 151, pp. 5328-5337) under the same ground as stated in the previous office action.

13. Applicants traverse and argue that the claims 73-88 recite particular amino acid and nucleotide sequence, and these sequences are not suggested in any of the three references cited by examiner. Applicants further cited that the situation of the instant case has a similar situation off In re Deule (34 USQ2d, 1212) because "the existence of a general method of isolating cDNA or DNA molecule is essentially irrelevant to the question of whether the specific molecules themselves would have been obvious..." Applicants further asserted that it is not proper for the examiner to use p38 protein identified in the "690" patent together with the methods described in the references to reject claims drawn to specific sequences.

14. Applicants' argument has been respectfully considered; however, it is not found persuasive because in the absence of the contrary that the protein p38 recognized by the monoclonal antibody C1.7 (ATCC HB 117170) of Patent "690" by Valainte et al. being the same to the claimed polypeptide, it is Applicants burden to approve that the claimed polypeptide does not have the same sequence of p38 protein since the claimed polypeptide and the p38 disclosed by Valainte et al. are isolated from same source (human NK cells stimulated with IL2, IL12), have same molecular weight (p38 Kd) and are recognized by the same monoclonal antibody (C1.7).

15. Because other two reference substantiated that method of using a molecular biology technique to molecular cloning and isolate an cDNA of a polypeptide, especially, the similar molecule of mouse homology of claimed product 2B4 has been cloned and subcloned into a vector and expressed in a mammalian cells for studying a similar function has been explicitly taught by Porunellor et al. A person with ordinary skill in the art would have been highly motivated to use the similar approach to isolate, clone or subclone the human version of 2B4 by using the technique that are already well described in the art in absence of unexpected result. Therefore, the rejection is maintained.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

May 14, 2003

James C. Housel 5/17/03
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
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